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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,755	04/23/2001	Vasily A. Topolkaev	44040-254221	4991

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EXAMINER

BOYD, JENNIFER A

ART UNIT PAPER NUMBER

1771

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/840,755

Applicant(s)

TOPOLKARAEV ET AL.

Examiner

Jennifer A Boyd

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 16-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 11, 2004 has been entered. The Applicant's Amendments and Accompanying Remarks, filed August 11, 2004, have been entered and have been carefully considered. Claims 1 is amended, claim 21 is added and claims 1 – 14 and 16 – 21 are pending. In view of Applicant's amendment requiring that the film is a "monolayer" and comprises a "blended mixture" of a biodegradable polymer and a water soluble polymer, the Examiner withdraws the previously set forth rejections as detailed in paragraphs 4 – 5 of the previous Office Action dated April 23, 2004. In view of Applicant's cancellation of claim 15, the objection as detailed in paragraph 2 of the previous Office Action dated April 23, 2004 has been withdrawn. However, after an updated search, additional prior art has been found which renders the invention as currently claimed unpatentable for reasons herein below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1 – 14 and 19 – 21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 – 5, 16, 20 – 21, 23 – 27 and 29 of copending Application No. 09/840754. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims teach a stretched biodegradable film comprising a biodegradable polymer and a water soluble polymer having a thickness from 0.01 to 5 mils, a water vapor transmission rate of greater than about 2500 g/m²/24 hrs and a elongation at break of greater than 100%. Additionally, Application No. 09/840754 teaches the same range of amount of water soluble polymer and biodegradable polymer present in the film and the same types of biodegradable and water soluble polymers.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

5. Claims 1 – 14 and 16 – 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (US 6,432,547) in view of Topolkaraev (US 6,586,354).

Kroll is directed to a breathable film layer composition (Title) useful in applications such as disposable articles such as disposable diapers, feminine napkins and medical devices and dressings (column 1, lines 10 – 17).

As to claims 1 and 21, Kroll teaches a composition useful for forming a film layer comprising a thermoplastic composition comprising *at least one* thermoplastic polymer and at least one diluent or radiation responsive composition (column 1, lines 55 – 60). Kroll teaches that the thermoplastic polymer can comprise water swellable polymers, water soluble polymers, water dispersible polymers or biodegradable polymers (column 2, lines 55 – 62). Kroll teaches that the WVTR is most preferably from 1000 to 2000 g/m²/day *or higher* (column 2, lines 40 – 44), meeting Applicant's requirement of greater than 2500 g/m²/day. Kroll teaches that the film is useful in applications such as disposable articles such as disposable diapers, feminine napkins and medical devices and dressings (column 1, lines 10 – 17).

As to claims 2 – 3, Kroll teaches that the WVTR is most preferably from 1000 to 2000 g/m²/day *or higher* (column 2, lines 40 – 44), meeting Applicant's requirement of greater than 3000 and greater than 3500 g/m²/day.

As to claims 4 - 5, Kroll teaches the use of polycaprolactone and polylactic acid as the biodegradable polymer (column 6, lines 15 – 22). It should be noted that polycaprolactone and polylactic acid are aliphatic polyesters as stated on page 6, lines 1 – 20 of Applicant's Specification.

As to claim 6, Kroll teaches the use of polyvinyl alcohol as one of the thermoplastic polymers (column 5, lines 5 – 15).

As to claim 7, Kroll teaches the use of polyethylene oxide as one of the thermoplastic polymers (column 5, lines 5 – 15).

As to claim 14, Kroll teaches that the film can be about 0.8 to 2 mils (column 2, lines 19 – 22).

As to claims 17 and 18, Kroll teaches that the film is useful in applications such as disposable articles such as disposable diapers, feminine napkins and medical devices and dressings (column 1, lines 10 – 17).

Kroll fails to teach that the film is stretched as required by claim 1 and specifically that the film is stretched 100 – 500 percent of its original length as required by claim 19. Kroll fails to teach that the film is laminated to a nonwoven web as required by claim 16.

Topolkaraev is directed to a microlayer breathable hybrid film of degradable polymers and thermoplastic elastomers (Title) suitable for diapers, feminine napkins, incontinence products and other applications (column 1, lines 15 – 30). . Topolkaraev teaches that the microlayer film comprises water degradable polymers and biologically degradable polymers (column 6, lines 40 – 50). Topolkaraev teaches that the microlayer film is subjected to stretching operations (column 11, lines 30 – 35) Topolkaraev notes that stretching can provide microporous microlayer film with a distinctive porous microlayered morphology, can enhance water vapor transport through the film, can improve water access, enhance the degradability of the film and enhance the elastomeric properties of the film (column 11, lines 30 – 40). Topolkaraev teaches that the film is stretched from about 100 to about 500 percent of its original length (column 11, lines 35 – 40). Topolkaraev teaches that the microlayer film can be laminated to one or more

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nonwoven webs (column 12, lines 20 – 25) making it suitable for applications such as absorbent personal care items (column 12, lines 20 – 27).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to stretch the film of Kroll between 100 – 500 percent of its original length as suggested by Topolkaraev motivated by the desire to enhance water vapor transport through the film, improve water access, enhance the degradability of the film and enhance the elastomeric properties of the film (column 11, lines 30 – 40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to laminate the film of Kroll to a nonwoven as suggested by Topolkaraev motivated by the desire to create a composite suitable for use in disposable personal care items as desired by Kroll.

As to claims 10 – 13, Kroll in view of Topolkaraev discloses the claimed invention except for that the biodegradable film comprises about 1 – 50% water soluble polymer as required by claim 10, comprises 5 – 30% water soluble polymer as required by claim 11, requires 50 – 99% biodegradable polymer as required by claim 12 and requires 70 – 95% biodegradable polymer as required by claim 13. It should be noted that the amount of water soluble polymer, amount of biodegradable polymer and amount the film is stretched are result effective variables. For example, as the amount of the water soluble polymer increases, the breathability and water sensitivity of the film increases. As the amount of biodegradable polymer increases, the biodegradability of the film increases. It would have been obvious to one having ordinary skill in the art at the time the invention was made to create the biodegradable film comprising about 1 –

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50% water soluble polymer as required by claim 10, comprises 5 – 30% water soluble polymer as required by claim 11, requires 50 – 99% biodegradable polymer as required by claim 12, requires 70 – 95% biodegradable polymer as required by claim 13 since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In the present invention, one would have been motivated to optimize the amount of biodegradable polymer, water soluble polymer and the amount the film has been stretched to create a film with optimal strength, water sensitivity and breathability.

As to claims 8 – 9 and 20, although Kroll in view of Topolkaraev does not explicitly teach the claimed elongation at break of greater than about 100% as required by claim 8, elongation at break of greater than about 200% as required by claim 9 and elongation at break of about 350% or greater as required by claim 20, it is reasonable to presume that said properties are inherent. Support for said presumption is found in the use of like materials (i.e. a biodegradable film comprising a composition of a blended mixture of a biodegradable polymer and a water soluble polymer which is stretched from about 100 – 500 percent of its original length) which would result in the claimed property. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed properties of elongation at break of greater than about 100% as required by claim 8, elongation at break of greater than about 200% as required by claim 9 and elongation at break of about 350% or greater as required by claim 20 would obviously have been present once the Kroll in view of Topolkaraev product is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977).

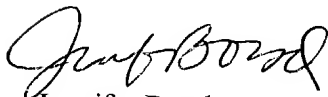
Response to Arguments

6. Applicant's arguments with respect to claims 1 – 14 and 15 - 21 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A Boyd whose telephone number is 571-272-1473. The examiner can normally be reached on Monday thru Friday (8:30am - 6:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jennifer Boyd
October 28, 2004



Ula C. Ruddock
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